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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,939	02/14/2007	Frederik W. Van Ginkel	20674-0003US1	2227

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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
12/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/578,939	VAN GINKEL ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-125* is/are pending in the application.

4a) Of the above claim(s) *20-37 and 46-125* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 38-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment filed September 3, 2009 has been received and entered.

Accordingly, claims 1-125 remain pending in the instant application, of which claims 20-37 and 46-125 are withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1-19 and 38-45 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a written description rejection is withdrawn in view of Applicants arguments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The rejection of claims 1-5, 18-19, 38 and 42 under 35 U.S.C. 102(b) as being anticipated by Tuomanen et al is withdrawn in view of Applicants amendment.

3. The rejection of claims 1-19, 38 and 42 under 35 U.S.C. 102(b) as being anticipated by Masignani et al is maintained.

Applicants are asserting that Massignani fails to specifically disclose or suggest an isolated detoxified pneumococcal neuraminidase sequence, much less, an isolated detoxified pneumococcal neuraminidase that maintains antigenicity or immunogenicity. Applicants further assert that Massignani fails to disclose or suggest methods of making and using isolated detoxified pneumococcal neuraminidases.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that Massignani fails to specifically disclose or suggest an isolated detoxified pneumococcal neuraminidase sequence, much less, an isolated detoxified pneumococcal neuraminidase that maintains antigenicity or immunogenicity. However, Applicants are again directed to the teachings of Massignani, specifically claim 3, which recites a "protein comprising a ***fragment*** of an amino acid sequence selected from the group consisting of…" (Emphasis added). Massignani et al further define such fragments to include 7 or more consecutive amino acids starting from the N-terminus (e.g., 8, 10, 12, 14, 16, 18, 20, 30, 40, 50, 60, 70, 80, 90, 100 or more). (See page 1). Given that neuraminidase is a protein identified in claim 3, every single one of the above described fragments would be structurally identical to the structural requirements set forth in the instant claims. For example, Applicants specification (page 15, lines 12-13 sets forth that "amino acid residues 383-387, 467-473, 541-546 or 610-616" can be substituted, ***deleted*** or altered to create a detoxified pneumococcal

neuraminidase. Every single one of the “fragments" disclosed by Massignani (7, 8, 10, 12, 14, 16, 18, 20, 30, 40, 50, 60, 70, 80, 90, 100 consecutive amino acids) starting from the N-terminus would lack amino acids 383-387, 467-473, 541-546 and 610-616. Accordingly, the structure described by Massignani is identical to the structural requirements set forth in the instant claims. Furthermore, while there are a considerable number of proteins identified in claim 3 of Massignani, one of skill in the art would be immediately drawn to the neuraminidase protein in light of the prior art of record. For instance, Jedrzejas (Microbiology and Molecular Biology Reviews Vol. 65, No. 2, pp 187-207, 2001; IDS 12/26/06 Ref AEE) set forth that neuraminidase is a virulence factor that is present on all strains of pneumococci. (See page 201). Jedrzejas further set forth that polysaccharide vaccines are limited in their potency due to poor immunogenicity, and that the addition of a protein significantly increases immunogenicity (e.g., Pneumococcal Surface protein A, Pneumolysin, ***Neuraminidase***, etc.) (See page 204). Consequently, one of skill in the art at the time of the invention would have readily chosen the neuraminidase from the list of proteins recited in claim 3 to create “fragments” for vaccination as contemplated by Massignani, having done so the resulting fragment would inherently be a “detoxified pneumococcal neuraminidase or an antigenic portion thereof” as required by the instant claim language.

Applicants further assert that Massignani fails to disclose or suggest methods of making and using isolated detoxified pneumococcal neuraminidases. However, Applicants are respectfully directed to their own claim language, which recites “isolated detoxified pneumococcal neuraminidase or an antigenic portion thereof.” Given that

Massignani specifically claims pneumococcal neuraminidase fragments (as small as 7 consecutive amino acid residues) for vaccination purposes, any arguments concerning methods of making or using is not relevant to a claimed product (e.g., protein). (See page 1 and claim 3 of Massignani).

The claims are directed to an isolated detoxified pneumococcal neuraminidase or an antigenic portion thereof.

Masignani et al (WO 02/077021) disclose of pneumococcal neuraminidase fragments (as small as 7 consecutive amino acid residues) for vaccination purposes. (See page 1 and claims).

Applicants specification (page 15) defines “detoxified” as a reduction or elimination in enzymatic activity.” Applicants specification further sets forth that this is accomplished via substitutions, ***deletions***, or alterations of amino acids in the active site of the neuraminidase." (Emphasis added).

Given that Masignani et al contemplate pneumococcal neuraminidase fragments (ranging from 7, 8, 10…30, 40, 50 amino acids, etc) starting at the N terminus, which would inherently be lacking the “active site of the neuraminidase” (i.e., detoxified) the disclosure of Masignani et al is deemed to anticipate the instantly claimed invention.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The rejection of claims 1-19 and 38-45 under 35 U.S.C. 103(a) as being unpatentable over Masignani et al in view of Lee et al is maintained.

Applicants are asserting that Masignani fails to disclose or suggest an isolated detoxified pneumococcal neuraminidase or antigenic fragment thereof. Applicants further assert that the detoxified pneumococcal neuraminidases claimed in the present application have surprising and unexpected properties, including that immunization with

NanA will offer protection against pneumonia, meningitis, otitis-media and sepsis.

Applicants arguments have been fully considered but are not found to be persuasive.

First, Applicants are asserting that Masignani fails to disclose or suggest an isolated detoxified pneumococcal neuraminidase or antigenic fragment thereof. However, this argument has been fully addressed in paragraph number three above.

Finally, Applicants further assert that the detoxified pneumococcal neuraminidases claimed in the present application have surprising and unexpected properties, including that immunization with NanA will offer protection against pneumonia, meningitis, otitis-media and sepsis. However, as set forth above, the antigenic fragments claimed by Masignani are identical to the structural requirements set forth in the claims, accordingly, any property of providing protection against multiple infections would be an inherent property based on the protein fragment described by Masignani being structurally identical to the requirements of the claims. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition

by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004). "[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."); Abbott Labs v. Geneva Pharms., Inc., 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed.Cir.1999).

The claims are directed to an isolated detoxified pneumococcal neuraminidase or an antigenic portion thereof, and wherein the neuraminidase is present in a nasal spray or nebulizer.

The teachings of Masignani et al are set forth above.

Masingnani et al do not teach of pneumococcal neuraminidase present in a nasal spray or nebulizer.

Lee et al (US Patent Number 7,202,056) disclose that at the time of the instant invention it was routine in the art to administer polypeptides for eliciting an immune response via nasal sprays or nebulizers. (See paragraph 0605).

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have taken the immunogenic polypeptides disclosed by Masingnani et al and create compositions for administration via nasal spray or nebulizer as taught by Lee et al.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
December 16, 2009